REMARKS

In the subject Office Action dated July 27, 2006, claims 1, 3, 4-11, 13, 15-20 were examined and new claim 21 was restricted and considered withdrawn. In response thereto, claims 1, 8, 13, 15 and 20 are amended, claims 2, 12, 14 and 21 are canceled, claim 22 is added, and claims 3-7, 9-11 and 16-19 remain under active prosecution. Applicants assert that the amendments are subject in the originally filed application and do not introduce new subject matter. Moreover, Applicants assert that these amendments present no new issues and should be admissible after final rejection.

Previously submitted new claim 21 was restricted under 35 U.S.C. 121 with claims 1-20 deemed to be drawn to a combination, classified in class 606, subclass 139 and claim 21 being drawn to a sub-combination, classified in class 606, subclass 153. Applicants maintain that the scope of the search was not expanded to encompass this subclass since the Examiner included this subclass in the Examiner Search Strategy line 42 so examining claim 21 was not burdensome. Applicants have canceled claim 21, but assert that a new claim 22 presents no new issues as being a claim depending from claim 1 that affirmatively claims, and thus narrows, the environmentally described anastomosis ring. New claim 22 is equivalent to claim 21 as rewritten in dependent form. Moreover, the amendments made herein to claim 1 to clarify its structure which is tailored to such a woven tube anastamosis ring device further clarifies that the subcombination is particularly suited to the use as part of the combination.

Claim 7 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner found that the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. A "syringe knife tip with a ball that translates and springedly withdraws into the veress needle" is not adequately described in the specification or the drawings. It is unclear as to what structure the term "syringe knife tip" is referring, and there is no drawing expressing this limitation.

In response thereto, Applicants' representative has added new FIGS. 15-19 with text references added to the Brief Description of the Figures paragraphs [0030]-[0034] that depict the structure described in original specification paragraph [0036], which has been revised accordingly. The veress needle portions were clipped from a U.S. Pat. No. 5,098,388

"VERESS NEEDLE ASSEMBLY" to Kulkashi, which the Applicants' representative located.

Before adding figures to illustrate the rather graphical textual description provided in the Origially Filed Specification, the Applicants' representative performed due diligence into just how commonly understood the term "Veress Needle" was and its use for insufflation in laparoscopic procedures. The following excerpts are a portion of what was readily located via an Internet Google search:

> "Veress needle. A needle equipped with a spring loaded obturator that is used for insufflation of the abdomen in laparoscopic surgery." http://www.biology-online.org/dictionary/Veress_needle
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> 1938, Janos Veress of Hungary developed a specially designed spring-loaded needle. Interestingly, Veress did not promote the use of his Veress needle for laparoscopy purposes. He used veress needle for the induction of pneumothorax. Veress needle is the most important instrument today to create pneumo-peritoneum. Veress needle consists of an outer cannula with a beveled needle point for cutting through tissues. Inside the cannula of verses needle is an inner stylet, stylet is loaded with a spring that spring forward in response to the sudden decrease in pressure encountered upon crossing the abdominal wall and entering the peritoneal cavity. http://www.laparoscopyhospital.com/history_of_laparoscopy.htm
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> "Veress needle. Veress needle was invented by a chest physician for aspiration of pleural effusion keeping in mind that its spring mechanism and blunt tip will prevent the injury of lung tissue. The Veress needle consists of a sharp needle with an internal, spring loaded trocar. The trocar is blunt ended with a lumen and side hole. Disposable and non disposable metal Veress needles are available commercial in different lengths i.e. long for obese patients, short for thin or pediatric patients. Veress needle is used for creating initial pneumoperitoneum so that the trocar can inter safely and the distance of abdominal wall from the abdominal viscera should increase. Veress needle technique is the most widely practiced way of access. Before using veress needle every time it should be checked for its patancy and spring action." http://www.laparoscopyhospital.com/laparoscopic_equipments_detail_4.htm
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> Rationale and Intended Use for the Veress Needle: A Translation of the Original Descriptive Article. Surgical Laparoscopy, Endoscopy & Percutaneous Techniques. 9(4):241, August 1999. Bridgewater, Franklin H. G. F.R.A.C.S., F.R.C.S.(Eng.); Mouton, Wolfgang G. M.S., M.D., F.M.H. Abstract: Summary: The technical development of equipment in the last decade has resulted in a rapid expansion in the range of procedures capable of being performed safely by a laparoscopic technique. For many procedures, the first step is induction of a pneumoperitoneum. This has inherent danger, and there is disagreement on the preferred technique. The Veress needle is an instrument developed in the 1930s that has continued to be used into the

1990s. In view of the controversy about its present role, the authors reviewed the article that provided the original description of the needle. This review demonstrates that the designer had a clear intention for its use and an understanding of the hazards involved. In his hands, the complications were few. A translation of the article from German into English is provided. (C) 1999 Lippincott Williams & Wilkins, Inc. http://www.surgical-laparoscopy.com/pt/re/slept/abstract.00019509-199908000-00001.htm;jsessionid=G11Ny3C9K6W0lcGZPGLjSkrQG0lYvPPqJJL0RlxQt4Q9YShP17hY!-2105890861-949856145!8091!-1

Based upon the great many commercially available veress needles that have been widely used since the 1930s, Applicants assert that the textual description provides enabling support for one of ordinary skill in the art to the subject matter of claim 7 and the new drawings. Acceptance of the new drawings and reconsideration and allowance of claim 7 is respectfully requested.

Claim 15 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner found that claim 15 recites the limitation "the first cannula" in line 2. There is insufficient antecedent basis for this limitation in the claim. Applicants thus have deleted the term "first" to obviate the rejection.

Turning to the substantive rejections in the subject Office action, claim 13 was rejected under 35 U.S.C. 102(e) as being anticipated by Suyker (US 6,485,496). Claim 1 was rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as an obvious matter of design choice from Suyker. Claim 3 was rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Kim (US 5,797,920). Claim 4 was rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker as a matter of design choice. Claims 5, 6 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Kim (US 5,797,920). Claims 7, 11, 17, 18 and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Suyker and Kim and further in view of Yeatman (US 6,451,029) and further as a matter of design choice. Claims 8, 9, 10 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Toledano (US 5,855,312) and further as a matter of design choice.

Turning to independent claim 13, the claim as amended recites in part that the first and second controls are independently actuable to allow independent actuation of either longitudinal end of the actuating member. Thereby, the claimed invention may provide a

capability particularly advantageous for anastomosis between two tissue lumens as described in original specification paragraph [0035] where actuation of a proximal half may allow pushing a proximal tissue lumen toward a distal tissue lumen or actuation of a distal half may allow pulling the distal tissue lumen toward the proximal tissue lumen.

Claim 13 rejected under 35 U.S.C. 102(e) as being anticipated by Suyker (US 6,485,496). The Examiner relied upon Suyker to "teaches a surgical instrument, comprising: ... a first control (proximal end of cannula 58) operative to compress a longitudinal end of the actuating member toward a center of the actuating member to actuate a respective portion of the received anastomosis ring; a second control (proximal end of shank 13) to compress another longitudinal end (60) of the actuating member toward the center of the actuating member to actuate the other respective portion of the received anastomosis ring forming a hollow rivet shape (Column 8, proximal lines 57-64)." Applicants assert however that Suyker fails to disclose the claim as amended wherein half actuation allows tissue positioning. Given the different nature of the devices compressed by the applier of Suyker, there is not a teaching or suggestion within Suyker to address such positioning, especially in the different nature of forming anastomosis for blood vessels as taught by Suyker where such positioning is inappropriate. Consequently, Suyker fails to anticipate nor render unpatentable the claimed invention of claim 13. Reconsideration and allowance of claim 13, as well as claims 15-20 that depend therefrom, is respectfully requested.

Turning to independent claim 1, the claim as amended recites in part a surgical instrument for an anastomotic ring device comprising a woven tube of wire having outer loops or ends which thermally deform and evert when inserted into walls of two adjacent lumens at a luminal interface of an anastomotic site, the ends of the tube everting to form petals in a manner which holds the luminal interface of the anastomotic site into apposition. To that end, the instrument includes a plurality of distal engaging surfaces, each formed on a respective distal leaf spaced away from the central portion and positioned to engage a selected outer loop of a distal portion of the unactuated, cylindrical anastomotic ring for pulling the engaged outer loop proximally and outwardly during actuation and includes a plurality of proximal engaging surfaces, each formed on a respective proximal leaf spaced away from the central portion and positioned to engage a selected outer loop a proximal portion of the unactuated, cylindrical anastomotic ring for pulling the engaged outer loop distally and outwardly during actuation.

Claim 1 was rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as an obvious matter of design choice. Applicants assert however that the claim as amended clarifies that the actuation of a woven cylindrical tube to a rivet shape includes engaging surfaces that position the longitudinal outer loops, both at proximal and distal ends of the woven tube to effect actuation. The compression of flat clips into a V-shape thus differs markedly from the claim as amended wherein compression is used rather than a pulling outwardly in combination with compression. Thus, the modifications necessary to Suyker are beyond mere design choices and no suggestion or motivation has been provided for modifying the applier of Suyker to work on a different class of anastomosis ring devices used in a different type of bodily lumen. Reconsideration and allowance of claim 1, as well as claims 3-11 and 22 that depend therefrom, is respectfully requested.

With further reference to claim 3 and claim 4, these claims recite further structure for independently actuating either longitudinal set of cantilevered petals. Claim 3 was rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Kim (US 5,797,920). Claim 4 was rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker as a matter of design choice. However, as discussed above with regard to claim 13, the ability to independently actuate either a proximal or distal half of an anastamosis ring device for the purpose of positioning one of a distal and a proximal tissue lumen is a unique capability that was not appreciated by the cited references and thus claims 3 and 4 should be patentable over them.

With further reference to claims 8, 9, 10, and 20, the claims as amended recite features for illuminating a distal tissue lumen. Given the relative translucence of gastric bodily lumens, the proximally directed illumination and/or illumination of the actuating member facilitates confirmation of placement of the anastomosis ring device, as discussed in the original Specification paragraphs [0022], [0032] and [0045].

Claims 8, 9, 10 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Toledano (US 5,855,312) and further as a matter of design choice. However, Applicants note that Toledano teaches an endoscopic lighting and viewing device that views a patent surface of body tissue and fails to illuminate proximally through translucent tissue walls. Consequently, the cited references fail to contemplate the problem

addressed by the claimed invention. Reconsideration and allowance of claims 8, 9, 10 and 20 is respectfully requested.

Conclusion

In light of the remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. If there are any additional matters which may be resolved by telephone or fax, Applicants encourage the Examiner to contact their representative, David E. Franklin at (513) 651-6856 or dfranklin@fbtlaw.com to expedite issuance of this application.

Because the application previously contained 18 claims with 3 independent claims and now contains, after amendment, 18 claims with 2 independent claims, no new fees are due. In addition, no extensions of time are necessary as this amendment is being filed within the three month period for response. The Commissioner for Patents, however, is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

CERTIFICATE OF MAILING

I hereby certify that a copy of this correspondence is being deposited with the US Patent Office by electronic transmission addressed to MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

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